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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/611,439

07/01/2003

Edward G. Parent

701-230

1934

7590

05/12/2005

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EXAMINER

CORDERO GARCIA, MARCELA M

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/611,439

Applicant(s)

PARENT ET AL.

Examiner

Marcela M Cordero Garcia

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 9, 11-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-8 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

RD

DETAILED ACTION

Acknowledgement is made of Applicants' response dated March 7, 2005.

Applicants elect without traverse Group II, claims 7-13, directed to a conjugate.

In addition, Applicants' election of the following species is acknowledged:

The biologically active conjugate species formed by:

P-O-(CH₂-CH₂-SO₂-CH=CH₂)_n, wherein n=1 and P is hyaluronan, with alpha-interferon.

Claims 7-13 are readable on the elected species.

The species was examined and found to be free of the prior art, however, please see new matter rejection below.

A second species from among those encompassed by the instant claims was chosen by the examiner, i.e., the biologically active conjugate species formed by:

P-O-(CH₂-CH₂-SO₂-CH=CH₂)_n wherein n=1 and P is dextran, with horseradish peroxidase.

Claims 7-8, 10 are readable thereon and presented for examination on the merits. Claims 9, 11-13 are withdrawn because they do not read upon examiner's elected species.

Specification

The amendment filed March 7, 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no

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amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Applicant's corrections changing the intermediate $\text{P-O-CH}_2\text{-CH}_2\text{-SO}_2\text{-(CH=CH}_2\text{)}_n$ to $\text{P-O- (CH}_2\text{-CH}_2\text{-SO}_2\text{-CH=CH}_2\text{)}_n$.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 7-8 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original claim 7 is drawn to a compound a conjugate formed by the intermediate $\text{P-O-CH}_2\text{-CH}_2\text{-SO}_2\text{-(CH=CH}_2\text{)}_n$ which has a very different scope than the amended intermediate $\text{P-O-(CH}_2\text{-CH}_2\text{-SO}_2\text{-CH=CH}_2\text{)}_n$. Applicant's indicate that the claim has been amended to correct the formula so as to indicate the repeating divinyl sulfone unit and that one of ordinary skill in the art would be able to determine such typographical error. However, based on the disclosure, Insufficient support is provided for the new formula. Applicant's are requested to

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precisely and definitely point out the support for the proposed amendment to claims 7-8 and 10.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 recites the limitations "the reaction product" and "the intermediate" in line

1. There is insufficient antecedent basis for these limitations in the claim.

Claim 7 is rendered vague and indefinite because it is unclear the use of "and a biologically active material". It is suggested applicant changes the phrase to –with a biologically active material—as to more specifically point out the formation of the conjugate instantly claimed.

Claims 8 and 10 depend directly or indirectly from the rejected claim and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Lihme et al. (US 5,543,332).

Lihme et al. teach a conjugate comprising the reaction product of the intermediate having the formula $P-O-(CH_2-CH_2-SO_2-CH=CH_2)_n$, wherein n is an integer and at least 1, and P represents a hydrophilic biopolymer and a biologically active material capable of being covalently and nucleophilically bonded to said intermediate (See entire document, e.g., examples 1-16 and claims).

Please note that dextran reads upon a hydrophilic biopolymer as evidenced by Lofas, page 831, lines 18-19. (Pure and Appl Chem, 1995).

Therefore, the reference is deemed to anticipate the instant claims above, as drafted.

Claims 7-8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Lihme et al. (WO 93/01498).

Lihme et al. teach a conjugate comprising the reaction product of the intermediate having the formula $P-O-(CH_2-CH_2-SO_2-CH=CH_2)_n$, wherein n is an integer and at least 1, and P represents a hydrophilic biopolymer and a biologically active material capable of being covalently and nucleophilically bonded to said intermediate (See entire document, e.g., examples 1-16 and claims).

Please note that dextran reads upon a hydrophilic biopolymer as evidenced by Lofas, page 831, lines 18-19. (Pure and Appl Chem, 1995).

Therefore, the reference is deemed to anticipate the instant claims above, as drafted.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcela M Cordero Garcia whose telephone number is (571) 272-2939. The examiner can normally be reached on M-Th 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Marcela M Cordero Garcia, Ph.D.
Patent Examiner
Art Unit 1654

MMCG 05/05


CHRISTOPHER R. TATE
PRIMARY EXAMINER